PRELOADED IMPLANTATION DEVICE

Background of the Invention

The invention pertains to a pre-loadable implantation device comprising a hollow needle and a body adjoining the needle, the body comprising an elongated part extending along the same axis as the needle, a plunger that can be displaced within the elongated part and the needle, the periphery of the plunger defining a channel in the elongated part, and a chamber capable of holding an implant. The invention also pertains to an implantation device that has actually been preloaded with an implant.

Implantation devices are known and serve to introduce a medicinal implant (small rod, pill, tablet, granule and the like which incorporates a pharmaceutically active substance) subcutaneously into humans or animals, or into subcutaneous tissue of humans or animals in an easy, effective and aseptic way.

The implanting of a pharmaceutical preparation subcutaneously or in subcutaneous tissue is normally used in human and veterinary medicine to achieve, e.g., prolonged action of the pharmacon. The implant introduced (small rod, pill, tablet, granule, etc.) slowly dissolves in the surrounding tissue or slowly releases the pharmacon thereto, and the pharmacon goes into circulation via the blood or the lymph in order then to be transported to the site or sites where it can perform its action. Thus, for example, in gynaecology a tablet containing an oestrogen, for example oestradiol, is implanted in women after double ovariectomy or in women during menopause in order to counteract or prevent certain symptoms from which these women suffer or may suffer. Such oestradiol, or other gynaecological implants are generally inserted subcutaneously into an area where there is relatively little movement, such as the upper outer quadrant of the buttock or the lower abdominal wall. In animals implants which contain hormones are, for example, introduced subcutaneously in order to regulate oestrus.

The invention, as noted above, is in the field of preloadable implantation devices. The term "preloadable" indicates that the device allows the implant to be present within the device before such device is used, i.e. by comprising a chamber capable of holding an implant. Such a chamber, which may have any shape suitable for any desired implant to fit into it, when provided beforehand with the implant (i.e. in the preloaded state) makes it easier to control the desired sterility. Particularly, the invention thus provides easy handling by a specialist or a general practitioner, as well as an easy administration *per se* of the implant: this can be done by simply pushing forward the plunger so as to displace it into the needle and thus insert the implant through the needle into the body.

Preloadable implantation devices of the aforementioned type are known. Thus, e.g. US 5,520,660 discloses a device for administering implants, which comprises an active substance container with injection cannula and plunger. The plunger is arranged in a plunger channel which merges into the lumen of the cannula. A holder-device for the implant is arranged at the lumen-end side of the plunger channel.

Another background art reference on preloaded implantation devices is EP 402 955, which discloses a syringe containing a capsule chamber, a hollow needle (removably) mounted at the front end of the capsule chamber, and a plunger, all mounted on a common axis so that the plunger can be passed through the capsule chamber and into the hollow needle to expel a capsule of a solid preparation from the chamber through the needle into a patients body.

Other disclosures on preloaded implantation devices having, positioned in line, a hollow needle, an implant-containing chamber and a plunger by means of which the implant can be pushed through the needle, include US 4,661,103, US 4,601,699, GB 2-138-298, EP 551 699, and FR 2,231,355.

The present invention provides an implantation device with which not only the above problems are solved, but which also avoids the drawbacks of more old-fashioned methods of subcutaneously introducing tablets containing an active substance. A known implantation device serving this purpose, has bene described in EP 564 038. A major drawback of the above preloadable implantation devices is that they do not enjoy the benefits associated with the implantation device according to EP 564 038.

To have these benefits, it must be possible for the needle to be chamfered at the distal end (tip), specifically in such a way that there is a sharp point with which the skin can be pierced, and is firmly joined at the proximal end to the body. The plunger too (also referred to as a mandrel) has a distal end (tip) which is chamfered, specifically at precisely the same angle as the hollow needle. Thus the plunger can be pushed into the hollow needle in such a way that the chamfered end precisely coincides with the chamfered end of the hollow needle, as a result of which a solid needle is, as it were, produced. With the solid needle formed in this way, the skin and the subcutaneous tissue is pricked at the site where it is desired to introduce the implant, normally at an oblique angle. The advantage of using a chamfered solid needle is that the tissue is split and not punched. As a result, the tissue is damaged to a lesser extent and the healing of the prick proceeds more quickly, virtually without leaving any scar. With a hollow chamfered needle, there is a greater possibility in that some tissue will enter the needle as a result of the punching action, the tissue damage therefore becomes somewhat greater and the healing of the prick lasts somewhat longer, with a greater probability of some visible scar.

The above-described preloadable implantation devices cannot be made to have such a provision. For, the plunger essentially must be in the pushed forward position (so as to enable the chamfered plunger tip to blend with the chamfered needle tip) when a patient is pierced with the needle. In the prior art devices this cannot be done without untimely displacing the implant from the chamber to outside the needle tip.

In EP 564 038, a way of operation has been disclosed which involves placing the implant into a chamber during use of the device, e.g. in a rather precise operation using tweezers. Other disclosures on implantation devices that require loading of the implant during operation include US 1,789,766, US 3,921,632 and DE 806 702. None of these known devices has a chamber capable of holding the implant. This also holds for other known injection devices which have specially designed needle-tips for which, by way of background, reference is made to US 2,751,907 and GB 2,199,247.

Summary of The Invention

As will be clear from the above, with the present invention it is sought to provide an implantation device which can be preloaded, thus making it possible to avoid the step of loading the device with the implant during use, but at the same time has the possibility of being provided with provisions that require the free displaceability of the plunger, such as a plunger which blends with the tip o f the needle, so as to avoid undue damage to the patient's tissue.

This object is fulfilled by the invention. To this end, the invention consists therein, that in an implantation device of the above-identified, preloadable type, the chamber is positioned radially outside the channel and has a directly or indirectly open connection to the channel, the plunger being capable of closing off and opening up the chamber by being displaced.

Although benefits of the present invention can be enjoyed in the case of implantation devices that neither have a chamfered needle tip, nor a chamfered plunger tip, it will be clear that it is preferred according to the invention to have such provisions. In that respect, the invention provides a particular improvement on implantation devices such as described in EP 564 038, US 3,921,632. Essentially, this is the type of devices which comprises a hollow needle with a chamfered tip profile and a body adjoining the needle part, the body comprising (a) an elongated part extending along the same axis as the needle, (b) a plunger that can be displaced within the elongated part and the needle, the plunger having a chamfered tip profile

capable of blending with the needle tip profile, wherein the periphery of the plunger defines a channel in the elongated part, and (c) a chamber capable of holding an implant. The chamber of these known devices not being preloadable, the present invention solves the problem of how to provide a preloadable device without losing the strong benefit of the chamfered plunger profile. As outlined above, the means to solve this problem is that the device is provided with a chamber that is positioned radially outside the channel and has a directly or indirectly open connection to the channel, whereby the plunger is capable of closing off and opening up the chamber by being displaced.

The closing off an opening up of the chamber can be by simple displacement of the plunger. I.e., the chamber has an opening of such dimensions at the side of the plunger that, when the plunger is pulled back to behind the chamber (i.e. is pulled to the rear end of the device, by which is meant the end facing away from the needle), an implant contained within the chamber will automatically fall into the plunger channel. It is also possible to make use of other forces than that of gravity, e.g. by providing the chamber, at the side facing away from the channel, with an elastic means such as a spring, which pushes the implant against the plunger when the chamber is closed off, and which makes the implant be pushed from the chamber into the channel when the plunger has been pulled back. Other means for the closing off of the chamber than just the plunger can be provided. Thus, other possibilities include a chamber closed off by an additional closing means, such as a door which automatically opens upon full withdrawal of the plunger, or any suitable mechanical, electronic or optical means steering the opening up of the chamber so that an implant contained therein can be displaced into the channel on or after the moment that the required space therein has become available by withdrawal of the plunger.

The requirement of the plunger being capable of closing off and opening up the chamber by being displaced not only refers to the way the open connection between the chamber and the channel has been made, it also refers to the longitudinal position of the chamber and the length of the plunger. It will be clear to the person

of ordinary skill in the art, that the plunger should be long enough to be pulled back to behind the chamber, and that it is preferred for the chamber to be at a sufficiently large distance from the rear end of the device so as to allow the plunger to be pulled back sufficiently and still be contained within the body of the device.

The device may contain suitable means to ensure that when the plunger is pushed fully into the needle, the chamfered needle point and the chamfered end of the mandrel coincide precisely. Possible means for providing this include a plunger end (i.e. at the side facing away from the needle) of in itself conventional type, which has a larger diameter than the plunger channel, and thus will prevent the plunger from being pushed forward any further than to the point at which said plunger end bumps against the plunger channel. Other means include a protrusion on the plunger and corresponding insertion in the wall of the plunger channel, *or vice-versa*, designed at such a position that when the plunger has been pushed forward to the desired distance, the protrusion will be fixed into the insertion (comparable to a principle known from an unrelated art, viz. that of well-known ball-points of the BIC® type).

As mentioned above, the chamber has a position radially outside the channel. In general, this means that the chamber has a position which, when the device is being used to administer an implant, can be described as being "above" the channel. By virtue of the direct or indirect open connection of the chamber to the channel, an implant contained within the chamber will actually fall into the channel (as a result of the action of gravity) when the plunger has been withdrawn (pulled backwards) so as to free the part of the channel directly underneath the chamber. Other embodiments, though, are not to be excluded, e.g. a chamber which has a position which, upon use of the device, can be described as being "underneath" the channel and which comprises a spring or the like which may forward an implant into the channel.

In the case of a needle having the, most preferable, chamfered tip and associated chamfered plunger, the device is asymmetric in respect of a virtual central axis. Thus a "bottom" and a "top" side of the device can be defined. In respect thereof, a preferred embodiment is as follows. Considering that the point of the chamfered needle, and consequently also the point of the chamfered plunger, preferably are situated at the bottom side, it is preferred for the chamber capable of holding the implant to be situated at the top side.

The component parts of the device according to the invention and the feeding of a preloaded implant is further explained hereinafter with reference to the schematic drawings.

The figures each depict, in longitudinal cross-section, a device according to the invention. The reference signs in each of the figures having the same meaning, all of the figures display an implantation device (1) having a hollow needle (2) and a body (3) adjoining the needle (2) the body comprising an elongated part (4) extending along the same axis as the needle (2), a plunger (5) that can be displaced within the elongated part (4) and the needle (2), the periphery of the plunger defining a channel (6) in the elongated part (4), and a chamber (7) capable of holding an implant (8).

In FIG.1 a device (1) is shown in which the chamber (7) containing the implant (8) is in the closed-off position. FIG.2 shows a device (1) in which the chamber (7) has been opened up by pulling back the plunger (5) and the implant (8) has been fed into the channel (6). FIG.3 is incorporated to show the further operation of the device (1), viz. the pushing forward of the implant (8) by means of the plunger (5).

The components of the device are generally made of a hard material, for example stainless steel. Certain parts of the device may also be made of a suitable plastic, for example a hard type of PVC, certain nylons, PTFE, acrylates such as PPMA, polypropene, polystyrene, polycarbonate or polyoxymethylene. Preferred synthetic

materials are those that are sterilisable, more particularly those that may withstand γ-sterilisation. Such materials are known to the person of ordinary skill in the art. Preferred synthetic materials are ABS (terpolymer of acrylonitrile, butadiene, and styrene) and SAN (copolymer of styrene and acrylonitrile). Without excluding the possibilities of using other than conventional materials for the needle part and said elongated part, or at least the distal parts thereof, these are generally made of metal, preferably stainless steel. The implantation devices of the invention can be manufactured using conventional techniques known to the person skilled in the art.

The body, which may serve as a handle part or may comprise an additional handle part, is thicker than the needle part and may be tubular, but it may also have a different cross section. The handle part should, of course, have a shape such that the device can easily be handled for the purpose for which the device is intended. Thus, recesses can be provided in which the fingers, for example thumb and index finger, fit in order to enable the device to be held firmly during use.

The implants to be contained within the chamber, and, consequently, the chamber itself, may have any shape. A frequently occurring shape is that of a rod of cylindrical or rectangular cross-section, such as in the case of an implantation tablet which contains oestradiol and which is made under the brand name Dimenformon by N.V. Organon Oss, The Netherlands. Other examples of implants that can be employed to make preloaded implantation devices according to the invention are oestradiol implants such as Riselle®, Meno-Implant®, contraceptive implants such as Implanon®, or other hormonal implants such as testosterone implants. The device of the present invention, besides being suitable for introducing hormonal implants can also be employed for implants containing other active substances than hormones, and can be employed for implantation in other types of tissue beyond lipid tissue.